REMARKS

Entry of the foregoing and further and favorable reconsideration of the subject application in light of the foregoing amendment and the following remarks:

Applicant respectfully submits that no new matter has been added.

Claims 1.3-6,8-26 and 30-33 were pending at the time the July 1, 2004 Office Action was issued.

Claims 1 and 8 have been amended. Support for the amended claims can be found generally throughout the instant Specification. No new matter has been added.

Accordingly, Claims 1,3-6, 8-26 and 30-33 are pending.

35 U.S.C. § 112, First Paragraph.

On page 3 of the July 1 2004 Office Action, Claims 1-10 are rejected under 35 U.S.C § 112 first paragraph in that the claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Specifically, the Examiner asserts that Claim 1 is deemed to contain new matter in regards to the limitation: "wherein the polyethylene oxide has a molecular weight greater than 250,000."

In response, support for Claim 1 as presently amended, can be found in the specification as originally filed in the parent application 09/751,160 on page 5, lines 19-20, page 8, lines 19-20 and page 13, lines 16-17. Accordingly, the Applicant respectfully requests that the Examiner withdraw the rejection.

Applicant notes that the Examiner suggested that "applicant file another application as a CIP application" in order to have a basis to claim the limitation of a polyethylene oxide molecular

weight range greater than 250,000. Applicant respectfully submits that the instant application refers throughout to "high molecular weight" polyethylene oxides. It would be clear to one of skill in the art that such a reference would encompass a wide range. However, it is generally accepted that with respect to such compositions high molecular weight polyethylene oxides are generally in a range greater than 350,000 to 500,000 at the lower limit. Indeed, applicant submits that when applicant specifically refers to polyethylene oxides of "high molecular weight" one of skill in the art would accept the limitation in a range greater than 350,000.

Applicant directs the Examiner's attention specifically to the language of the specification at page 5, beginning at line 19 and continuing into the top of page 6, wherein the applicant discloses "still another embodiment of the present invention, the polyethylene oxide is a high molecular weight polyethylene oxide. Still, according to another embodiment of the present invention, the polyethylene oxide is of a density of about 0.5 grams/ml. Further still, according to an embodiment of the present invention, the polyethylene oxide is of a molecular weight in the range of about 100,000 to 8,000,000." Applicant's description of "high molecular weight polyethylene oxide" provides a basis for one of skill in the art, which recognizes high molecular weigh polyethylene oxide as that which is greater than about 350,000 to 500,000 as a lower limit. Applicant's disclosure of an alternative embodiment, wherein the polyethylene oxide is of a molecular weight in the range of about 100,000 to 8,000,000 would not confuse or teach one of skill in the art away from a high molecular weight polyethylene oxide of 350,000 to 8,000,000 as distinct from a polyethyne oxide of 100,000 to 8,000,000. In support of applicant's position, please find Sheftel, VO. *Indirect Food Additives and Polymers: Migration and Toxicology*. Lewis 2000 pp.1114-1116, attached hereto as Exhibit A., and references therein.

Accordingly, applicant respectfully submits that the application is in compliance with the requirements of 112, first paragraph.

35 U.S.C. § 102(b) and 35 U.S.C. § 103(a).

On pages 4-5 of the July 1, 2004 Office Action, Claims 1, 3-6, and 11-14 are rejected under 35 USC § 102 as anticipated by or in the alternative, USC § 103 as obvious over Roth, US Patent No. 5,418,006. The Examiner notes "Roth et al may differ from applicant's claimed invention in that it is unclear what the molecular weight is of the carboxylmethylcellulose used in Examples 4-5. However, the Examiner asserts that it would be obvious for one of skill in the art to use the range as claimed by the applicant. On page 5 of the July 1, 2004 Office Action, Claims 9-10 and 30-33 are rejected as obvious over Roth. The Examiner notes that Roth does not teach the coating comprising a coloring agent a gfragrancing agent or one of applicant's specifically claimed polyethylene oxide species or surfactant species, but asserts that the broad disclosure of Roth renders such a teaching obvious.

Applicant respectfully submits that Roth teaches an impregnating agent which renders the substrate water repellent, and subsequently forming a coating by applying to the treated surface an aqueous composition containing an aqueous solution, dispersion and/or emulsion of a film-forming substance and a water-repellent substance. Applicant is clearly teaching the composition as an additive to coloring agents such as paints, which is distinct from the possibilities "obvious" to one of skill in the art given Roth's metal oxides. Moreover, there is no suggestion in Roth as to the other species claimed by applicant. The present invention is distinct both its approach and composition.

Accordingly, Applicant respectfully submits that the claims as presently amended overcome the rejections under 35 U.S.C. § 102 as anticipated by or in the alternative § 103 as obvious over Roth.

On pages 5-6 of the July 1, 2004 Office Action, the Examiner rejects Claims 1,3-6, 8-14 and and 30-33 under 35 U.S.C. §102(b) as anticipated by or in the alternative under 35 U.S.C. §103(a) as obvious over Muryama U.S. Patent No. 5,401,495. On page 7 of the July 1, 2004 Office Action, the Examiner also rejects Claim 7 under 35 U.S.C. § 103(a) as being unpatentable over Murayama, asserting that it would have been notoriously obvious to apply addition amounts of the composition to a surface. The Examiner notes that Murayama may differ from applicant's claimed invention in that it is unclear what the molecular weight is of the carboxylmethylcellulose 7MF component used in Example 4. However, the Examiner asserts that it would be obvious for one of skill in the art to use the range as claimed by the applicant, since such a molecular weight range is deemed to come directly within the broad disclosure of the patent.

In response, the Applicant respectfully submits that the claims as presently amended overcome the rejections under 35 U.S.C. 102(b) and 35 U.S.C. § 103(a) over the cited prior art. Specifically, Murayama does not teach the invention as now claimed. Murayama teaches a teeth whitener composition, which "has the ultimate effect of 'staining' the teeth white by absorption." Murayama at column 6, line 45-46. This composition, which is not removable, functions to "bleach" the teeth by absorbing titanium dioxide particles into the enamel of the teeth. The instant invention as now claimed is a composition, which can be removed from the surface at about room temperature with a solvent, which is distinct from the cited prior art reference.

Moreover, the Examiner notes that the carboxylmethylcellulose 7MF used in Example 4 has a molecular weight that is outside of applicant's claimed range (of 250,000), it would be bosious to use a molecular weight greater than 250,000. Applicant respectfully submits that Murayama does not teach "high molecular weight" (i.e. greater than 350,000 to 500,000 as a lower limit) nor is there such a suggestion to use high molecular weight polyethylene oxides as presently claimed.

Accordingly, Applicant respectfully submits that the amended application is not anticipated or rendered obvious by the cited prior art references and urges the Examiner to withdraw the rejection of claims 1,3-6, 8-14 and 30-33 under 35 U.S.C. 102(b) as anticipated by Murayama or in the alternative under 35 U.S.C. §103(a) as obvious over Murayama and claim 7 under 35 U.S.C. §103(a) over Murayama.

On pages 7-8 of the July 1, 2004 Office Action, claims 1-10 are rejected under 35 U.S.C. §103(a) as unpatentable over Sramek U.S. Patent No. 4,861,583. The Examiner notes that Sramek differs from applicant's claimed invention in that there is no direct teaching of a hair treatment composition that actually comprises a water soluble polyethylene oxide that has a molecular weight of greater than 250,000. However, the Examiner asserts that it would be obvious for one of skill in the art to make and use a hair treatment composition that contained a water-soluble polyethylene oxide polymer having a molecular weight greater than 250,000 since Sramek directly discloses and claims the use of polyethylene oxide within a range of between 20,000 and about 250,000. The Examiner asserts that Sramek's use of the modifier "about" clearly expands Sramek's disclosure to encompass a range "somewhat in excess of 250,000.

In response, the Applicant respectfully submits that the claims as presently amended overcome the rejections under 35 U.S.C. § 103(a) over the cited prior art. Specifically, Sramek does not teach the invention as now claimed.

Applicant respectfully submits that the amended application is patentable over Sramek under 35 U.S.C. 103(a) because it would not have been obvious to one having ordinary skill in the art to use the disclosure of Sramek as motivation to make the claimed composition which is capable of being removed from the surface at room temperature. There is no direct teaching in the cited prior art reference of the instant invention as now claimed. Moreover, there is no suggestion in the cited prior art reference to do so.

Accordingly, Applicant respectfully submits that the amended application is not rendered obvious by the cited prior art reference and urges the Examiner to withdraw the rejection of claims 1-10 35 U.S.C. 103(a) over Sramek.

Applicant respectfully submits that Rejections cited in paragraphs 7-11 of the July 1, 2004 Office Action are obviated in view of the presently amended claims. Applicant has responded by describing the referenced patents and how they differ from and fail to teach the Applicant's invention. The descriptions of referenced patents follow the legal references forming the basis for allowance under 35 U.S.C. Applicant has amended the claims, which are now in compliance with 35 U.S.C. 102(b) and 35 U.S.C. 103 (a).

With regard to any proposed combination of the cited prior art references, it is well known that in order for any prior art references themselves to be validly combined for use in a prior art §103 rejection, the references themselves (or some other prior art) must suggest that they be combined. In re Sernaker, 217 U.S.P.Q. 16 (CAFC 1983).

Prior art references in combination do not make an invention obvious unless something in the prior art references would suggest the advantage to be derived from combining their teachings. The suggestion to combine the references should not come from applicant. Orthopedic Equipment Co. v. United States, 217 U.S.P.Q. 193, 199 (CAFC 1983); Uniroyal, Inc. v. Rudkin-Wiley Corp., 5 U.S.P.Q. 2d 1434 (C.A.F.C. 1988) ("where prior-art references require selective combination by the court to render obvious a subsequent invention, there must be some reason for the combination other than the hindsight gleaned from the invention itself...Something in the prior art must suggest the desirability and thus the obviousness of making the combination.").

CONCLUSION

For the foregoing reasons, Applicant respectfully submits that the application and amended claims are now in proper form for allowance and that the amended claims are patentable over the prior art.

Therefore, Applicant respectfully submits that the application is now in condition for allowance, namely Claims 1,3-6, 8-26 and 30-33.

If for any reason this application is not believed to be in full condition for allowance, applicant respectfully requests the constructive assistance and suggestions of the Examiner pursuant to M.P.E.P. 706.03(d) and 707.07(j) in order that the undersigned can place this application in allowable condition as soon as possible without the need for further proceedings.

In the event that there are any questions concerning this Amendment, or the application in general, the Examiner is respectfully urged to telephone the undersigned so that prosecution of the application may be expedited.

No fee, other than the $510.00 fee for a three-month extension of time, is deemed necessary in connection with the filing of this Amendment.

Respectfully submitted,
STEIN & STEIN

By: _____ 1/3/2005
Steven B. Stein
Reg. No.: 43,159

STEIN & STEIN
114 Old Bloomfield Ave.
Parsippany, NJ 07054
(973) 882-8820

Date: January 3, 2005

Polyethylene Glycols (PEGs)

Sheftel, VO. ***Indirect Food Additives and Polymers: Migration and Toxicology.*** **Lewis 2000 pp.1114-1116**

Structural Formula. $HO[\sim CH_2CH_2O\sim]_nH$
M = 500,000 to 10,000000
CAS No 25322-68-3
RTECS No TQ3500000
Abbreviation. PEGs.

Synonyms and Trade Names. Carbowaxes; 1,2-Ethanediol, homopolymers; Ethylene glycol, homopolymers; Ethylene oxide, polymers; Ethylene polyoxide; Lutrol; Oxyethylene polymer; Polyethylene oxide polymers; Poly(ethyleneoxide)s; Polyhdroxyethylene; Polyoxyethylene; Polyoxyethylenediol; Poly(oxyethylene) glycols; Poly(vinyl oxide).

Properties. Clear, viscous liquids (M = 200 to 600) or waxiform (M = 1000 to 6000) products. Solubility in water is inversely proportional to molecular mass. Liquid PEG are colorless, almost odorless, and miscible with water. Waxiform PEGs (carbowaxes) are soluble in water (50 to 73%). At a concentration of 1.0 g/1, they do not alter the color, odor, or taste of water.

Applications. Used in food and food packaging. Used as plasticizers, solvents, water-soluble lubricants for rubber molds; wetting or softening agents, antistatics in the production of urethane rubber, components of detergents, etc. In medicine, PEGS are used in cosmetics, ointments, suppositories, in ophthalmic solutions and sustained-released oral pharmaceutical applications.

Migration of up to 50 mg PEGs/kg food was observed in chocolates, boiled sweets, toffees, cakes, and meat pies that were wrapped in regenerated cellulose films containing various mixtures of glycol softeners. Analysis of the glycols were performed by capillary GC with flame ionization detection after trimethylsilyl derivatization.[1]

Acute Toxicity. PEGs are generally considered to be inert and possess a low order of toxicity in animals and humans. Administration of 0.5 g high-molecular-mass PEG/kg BW in the form of an aqueous solution caused no visible signs of intoxication. No mortality occurred. Histological examination revealed small areas of round-cell infiltration, expanded vessels in the kidneys, and a plethoric spleen.2 A dose of 2.5 g/kg BW of PEG with M = 2,000000 and

7,000000 was not lethal to rats or mice. In the last case, the acute effect threshold was 0.5 g/kg BW. In the same doses, PEG synthesized on an organocalcium compound was not lethal. The acute effect threshold was not established.[3]

The mean lethal doses of PEG are presented in the table.[03]

Table Mean lethal doses of PEGs (g/kg BW).

Polyethylene Glycols	Mice	Rats	Guinea pigs	Rabbits
200 (insoluble)	33.9-38.3	28.9	16.9	14.1-19.9
300 (insoluble)	31.0	27.5-31.1	19.6-21.1	17.3-21.1
400 (insoluble)	28.9-35.6	12.9-30.2	15.7-21.3	22.3
600 (insoluble)	35.6-47.0	38.1	28.3	18.9
1000 (50%aqu.sol.)	>50	42.0	22.5-41.0	>50
4000 (50%aqu.sol.)	>50	>50	46.4-50.9	>50
6000 (50%aqu.sol.)	>50	>50	>50	>50
9000 (50%aqu.sol.)	>50	>50	>50	>50

Repeated Exposure. Cumulative properties were observed only in PEG obtained on an organoaluminum catalyst. Administration of 50 mg/kg BW over a period of two months decreased STI. An increase in BW gain was noted. A dose of 250 mg/kg BW caused a reduction in erythrocyte count and in peroxidase activity of the blood.

Cumulative properties of other PEGs were not pronounced: doses of 20 and 50 mg/kg BW did not kill animals. $K_{acc} = 5$.

Short-term Toxicity. F344 rats received up to 30,000 ppm NF-10 grade Polyox (M = about 100,000) in the diet for 13 weeks. The treatment caused slight increases in food consumption, BW, and BW gain. A dose-related increase in liver weight was not associated with any histopathology.[4]

Long-term Toxicity. Rats and mice received 3.1 g PEG/kg BW in aqueous solutions (M - 5,000000) for 12 months. There were no manifestations of toxic action.[2]

A 2-year dietary dosage up to 20,000 ppm NF-10 grade Polyox produced no toxic effects in treated rats.

There was no neoplastic and non-neoplastic pathology observed in this study.[4]

Allergenic Effect. Sensitizing properties were not pronounced.

Reproductive Toxicity. In a 2-year feeding study, oral and parenteral administration of PEG caused no effect on reproduction.[5]

See also ***Diethylene glycol***.

Gonadotoxicity. In a 90-day study, administration of the dose of 230 mg PEG-75/kg BW induced testicular tubule degeneration and oligospermia.[6]

Rats received a dose of 3.0 mg/kg BW. The treatment caused no effect on the gonads or embryos, nor did it affect reproduction or the development of offspring.[2]

Rats were injected i/p with doses equivalent to 0.5 LD50 of PEG-400 and PEG-1500 three times during the gestation period. No increase in pre-implantation mortality was observed.

Embryotoxicity. Mild signs of embryotoxicity together with generally retarded development were reported..

No ***teratogenic*** effect was noted.'

Mutagenicity.

In vitro genotoxicity. Polyox showed neither genotoxic activity in Salmonella typhimurium and E. coil assays, nor did it cause CA in Chinese hamster ovary cells.7

In vivo cytogenetics. Polyox was found to be negative in mouse bone marrow micronucleus test.[4]

Carcinogenicity. Exposure to PEG resulted in vaginal tumors and a weak tumor initiator effect in mice.[5,8,9]

Chemobiokinetics. Polyox is not absorbed in the GI tract. It showed high recoveries. Essentially all radiolabel was excreted in the feces.4 After i/v administration, PEG are excreted mainly unchanged. Regulations.

EU (1990). PEGs are available in the List of authorized monomers and other starting substances which shall be used for the manufacture of plastic materials and articles intended to come into contact with foodstuffs (Section A).

U.S. FDA (1998) regulates PEGs for use (I) in adhesives used as components of articles

intended for use in packaging, transporting, or holding food (PEG 200-6000) in accordance with the conditions prescribed in 21 CFR part 175.105; (2) in resinous and polymeric coatings used as the food-contact surfaces of articles intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food in accordance with the conditions prescribed in 21 CFR part 175.300; (3) as a component of the uncoated or coated food-contact surface of paper and paperboard intended for use in producing, manufacturing, packing, transporting, or holding dry, aqueous and fatty food in accordance with the conditions prescribed in 21 CFR parts 176.170 and 176.180; (4) as a component of defoaming agents that may be safely used as components of articles intended for use in contact with food in accordance with the conditions prescribed in 21 CFR part 176.200; (5) PEG (M = 200 to 4600) of as defoaming agent used in the manufacture of paper and paperboard intended for use in packaging, transporting, or holding food in accordance with the conditions prescribed in 21 CFR part 176.210; (6) in the manufacture of cross-linked polyester resins for repeated use in articles or components of articles coming in the contact with food (PEG-6000) in accordance with the conditions prescribed in 21 CFR part 177.2420; (7) as a substance employed in the production of or added to textiles and textile fibers intended for use in contact with food (PEG 400 to 6000) in accordance with the conditions prescribed in 21 CFR part 177.2800. PEG may be safely used (8) if the additive is an addition polymer of ethylene oxide and water with a mean molecular mass of 200 to 9,500 and if PEG contains no more than 0.2% by weight of the ethylene and diethylene glycols and if its molecular mass is 350 or higher and no more than 0.5% by weight of the total of ethylene and diethylene glycols and if its mean molecular mass is below 350.

PEG monolaurate (PEG-400) containing not more than 0.1 % by weight of the ethylene and/or ethylene glycol may be used at a level not to exceed 0.3% by weight of the twine as a finish on twine to be used for tying meat provided the twine fibers are produced from nylon resins.

PEG dilaurate (PEG-200) may be used as a component of the uncoated or coated food-contact surface of paper and paperboard intended for use in producing, manufacturing, packaging, processing, preparing, treating, packing, transporting, or holding dry foods in accordance with the conditions prescribed in 21 CFR part 176.180. PEG alginate is listed for use as a component of the uncoated or coated food-contact surface of paper and paperboard intended for use in producing, manufacturing, packing, transporting, or holding aqueous and fatty food in accordance with the conditions prescribed in 21 CFR part 176.170.

Great Britain (1998). PEGS are authorized without time limit for use in the production of

polymeric materials and articles in contact with food or drink or intended for such contact.

Recommendations.

Joint FAO/WHO Expert Committee on Food Additives. ADI: 10 mg/kg B W. Russia. ADI: 100 mg/kg BW.[2]

Standards. ***Russia.*** PML: n/m. MAC depends on M (organolept., foam): [3]

0.125 mg/l for PEG with M = 2,000000;

0.1 mg/l for PEG with M = 3,000000;

0.2 mg/l for PEG with M = 5,000000.

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